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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,199	07/30/2003	Juergen Wulf	GK-OEH-163 / 500814.20065	2020
7590	10/19/2006		EXAMINER	
Gerald H. Kiel, Esq. REED SMITH LLP 599 Lexington Avenue New York, NY 10022-7650			LEVKOVICH, NATALIA A	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,199

Applicant(s)

WULF ET AL.

Examiner

Natalia Levkovich

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/08/2006 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 'diodes separated alike the nozzle pitch of the comb by a multiple of the well's pitch, the unit fitting exactly into the holder of the dispensing comb', as recited in claim 22, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

Art Unit: 1743

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 recites an 'alignment unit' having two diodes, the 'unit fitting exactly into the holder of the dispensing comb. Upon review of the original specification, the Examiner

Art Unit: 1743

found no support for the above limitation. The specification discloses an 'adjustment comb' [not 'alignment unit'] with light sources [not diodes] and does not specify structural inter-relationship between the 'adjustment comb' and the 'dispensing comb holder'. The latter also lacks support in the written description. Thus, the limitation is considered to be new matter and must be cancelled from the claim.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 1 recites 'an optical system by which the luminescent light that is excited in the wells of the microplate due to the dispensing is transferred to an imaging camera'. The claim further recites the 'imaging camera being directed by said optical system to the underside of the microplate across from the dispensing unit for imaging all wells of a large-area rectangular field of observation of the microplate, wherein said large-area rectangular field includes a plurality of columns being progressively dispensed, so that a time-dependent luminescence behavior of the individual specimens in the wells of each dispensed column is measurable over time while simultaneous ongoing dispensing occurs in all wells of said rectangular fields of the microplate successively column by column'. First, it is not clear how the 'optical system for 'transferring light' can 'direct' the camera in a certain way, since orienting the camera in a certain direction would require some mechanical means. Second, it is

Art Unit: 1743

unclear what elements of the claimed structure would provide for the underlined functionality.

In claim 22, line 4, 'the holder of the dispensing comb' lacks antecedent basis. Is Applicant intending the 'adapter holder' or 'microplate holder' recited in claim 19 ?

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-5, 8-9, 11-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler et al. (US 20020176801).

As was previously discussed, Giebeler discloses an integrated fluid delivery and analysis system comprising a light tight housing with a door, a dispense assembly, a

Art Unit: 1743

light source, a detector, and an optical system "adapted to direct light from the light source to a sample holder such as a microplate positioned in an examination site, and from the sample holder to the detector..." (See [0030], [0033]). "FIG. 5 shows a perspective view of an exemplary material exchange system ['table system' – Ex.] 552... for supporting one or more material holders 556 ..."- [0069]. The dispense assembly comprises "a compact modular folded pipettor head ['dispensing comb' having a symmetric structure – Ex.]-(See [0046]; Figures 6-7).

"The pipettor ['dispensing comb' – Ex.] may include a linear array of 8, 16, or any other number of appropriately spaced pipettor elements to correspond to a single row of a 96-well, 384-well, or any other number of well microplate, respectively. The pipettor also may include a linear array of 12 or 24 appropriately spaced pipettor elements to correspond to a single column of a 96-well or 384-well microplate, respectively. The pipettor also may include a number and arrangement of pipettor elements to correspond to a portion of a row or column, or two or more rows or columns, or another type of sample holder. The dispense assemblies may be easily interchangeable on the dispense assembly driver to accommodate microplates and other sample holders with different numbers and/or densities of wells"-[0060].

"The analyzer module preferably includes top and bottom optics, enabling a variety measurement modes, including... bottom illumination and bottom detection..."

The "sample holders" [wells – Ex.] may have "optically transparent bottoms, such as glass or thin plastic bottoms..."-[0087].

Art Unit: 1743

Giebeler does not teach a 'controllable pump for metering the amount of liquid to be dispensed without immersion in wells of the microplate'. However, such 'controllable pumps' for metering liquids, for example, syringes, are notoriously well known in the art. Additionally, Giebeler does teach in [0049] plus, that 'the dispense assembly may use noncontact and/or contact dispense mechanisms. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed controllable metering pumps, such as syringes, in the modified apparatus of Giebeler, in order to dispense some predetermined volumes of liquids.

Note that the 'imaging camera' is not positively claimed. Therefore, it is not considered to be a part of the claimed invention and is not accorded any patentable weight. The same considerations apply to claims 14-18.

With respect to claim 3, Giebeler teaches that an "eight-channel dispense assembly for a 96-well microplate may be used to dispense into a 384-well microplate by combining a first dispense into a first set of eight wells, an offset, and a second dispense into the second set of eight wells"-(See [0065]).

As to claim 4, Giebeler teaches that "the pipettor also may include a number and arrangement of pipettor elements to correspond to ... two or more rows or columns, or another type of sample holder" which reads on 'dispensing combs which are arranged parallel to one another, rigidly coupled with one another'.

Referring to claims 5 and 8, Giebeler teaches "a variety of dispense and/or analysis strategies, independently or in conjunction with one another", for example, the dispense may be "of the same reagent from a reservoir with the same format as a

Art Unit: 1743

microplate, to all wells in the sample holder, or even multiple reagents at different times”
-[0127].

In regards to claim 19, Figure 11 shows a sample-plate holding fixture (or carriage) 1101 designed to accommodate multiwell plates of standard dimensions (e.g., 86 by 129 millimeters). To accommodate other sized plates, an adaptor plate (not shown) is mounted within fixture 1101, the non-standard plate fitting within the adaptor plate”- [0098].

10. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler in view of Wohlstadter et al (20040022677).

Giebeler does not teach means of autofocusing and alignment. Wohlstadter discloses optics that “collects an image and focuses that image’ automatically (See [0520]) and “mechanisms to align and orient the assay plates with the photodetector(s) “ (See [0016]). As to light emitting diodes, focusing lenses, batteries and power switches, these elements are routinely used in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed means of alignment and auto-focusing , in the modified apparatus of Giebeler, in order to provide automatic control of high quality imaging system.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler in view of Marouiss et al. (US 20010048899).

Giebeler does not teach controllable valves for dispensing units, however such valves are routinely used in the art (see, for example, [0163], [0171], [0176] of Marouiss). It would have been obvious to one of ordinary skill in the art at the time the invention was

Art Unit: 1743

made to have employed controllable valves with the dispensing units in the modified apparatus of Giebeler, in order to monitor the dispensing process.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler in view of Marouiss, and further view of Schick (US 20030230521).

Giebeler does not teach a waste trough, however, waste containers are commonly used in the liquid handling systems (see, for example, [0044]-[0045] of Schick). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed waste containers arranged in a suitable manner, in the modified apparatus of Giebeler, in order to provide a proper waste removal.

Allowable Subject Matter

13. Claim 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Although the closest prior art, Marouiss et al., disclose a linear dispensing unit adapted to microplates with different distances between the wells through offsetting the entire unit relative to a microplate, Marouiss et al do not teach, or fairly suggest a linear dispensing unit which includes two parallel units arranged offset to one another by half of the distance between the dispensing nozzles, as recited in claim 10.

Response to Arguments

14. Applicant's arguments filed on 08/08/2006 have been fully considered but they are not persuasive and moot in view of new grounds of rejection.

Applicant argues that 'Giebeler only observes at best on column per time by using separate photomultipliers for each single well' and 'does not teach or suggest the large-area rectangular field'. Examiner disagrees. Giebeler teaches different embodiments where the imaging device can be selected from "photodiodes, photodiode array, avalanche photodiodes or avalanche diode array or a suitable CCD (rectangular or square, cooled to a suitable temperature to insure adequate signal to background ratio)" - (see [0247]). Additionally, imagers providing a 'large area field' for simultaneous observation of a number of wells, are very well known. For example, Wohlstadter teaches in [0505] that the "active surface of photodetector ... such as a CMOS or CCD chip) is preferably matched to the size of the object (e.g., individual well, multi-well assay plate sector or multi-well assay plate) being imaged so as to balance the requirements for light capturing efficiency and the spatial resolution of the recorded image with the cost and size of the detector (and associated optics). Preferably, the area of the active surface or imaging surface of the photodetector is 25% to 200% of the area being detected or imaged or more preferably between 50% and 100%". Finally, Examiner reminds that the imaging camera and the related limitations are not accorded patentable weight for the reasons discussed above.


Art Unit: 1743

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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